

**§ 890.5290 Shortwave diathermy.**

(a) *Shortwave diathermy for use in applying therapeutic deep heat for selected medical conditions*—(1) *Identification*. A shortwave diathermy for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of the body electromagnetic energy in the radio frequency bands of 13 megahertz to 27.12 megahertz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies.

(2) *Classification*. Class II (performance standards).

(b) *Shortwave diathermy for all other uses*—(1) *Identification*. A shortwave diathermy for all other uses except for the treatment of malignancies is a device that applies to the body electromagnetic energy in the radio frequency bands of 13 megahertz to 27.12 megahertz and that is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues as described in paragraph (a) of this section.

(2) *Classification*. Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required*. No effective date has been established of the requirement for premarket approval for the device described in paragraph (b)(1). See § 890.3.

[48 FR 53047, Nov. 23, 1983, as amended at 52 FR 17742, May 11, 1987]

**§ 890.5300 Ultrasonic diathermy.**

(a) *Ultrasonic diathermy for use in applying therapeutic deep heat for selected medical conditions*—(1) *Identification*. An ultrasonic diathermy for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of the body ultrasonic energy at a frequency beyond 20 kilohertz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies.

(2) *Classification*. Class II (performance standards).

(b) *Ultrasonic diathermy for all other uses*—(1) *Identification*. An ultrasonic diathermy for all other uses except for the treatment of malignancies is a device that applies to the body ultrasonic energy at a frequency beyond 20 kilohertz and that is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues as described in paragraph (a) of this section.

(2) *Classification*. Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required*. No effective date has been established of the requirement for premarket approval for the device described in paragraph (b)(1). See § 890.3.

[48 FR 53047, Nov. 23, 1983, as amended at 52 FR 17742, May 11, 1987]

**§ 890.5350 Exercise component.**

(a) *Identification*. An exercise component is a device that is used in conjunction with other forms of exercise and that is intended for medical purposes, such as to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. Examples include weights, dumbbells, straps, and adaptive hand mitts.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807. The device also is exempt from the current good manufacturing practice regulations in part 820, with the exemption of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

**§ 890.5360 Measuring exercise equipment.**

(a) *Identification*. Measuring exercise equipment consist of manual devices intended for medical purposes, such as to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. These devices also include instrumentation, such as the pulse rate monitor, that provide information used for physical evaluation and physical planning purposes. Examples include a therapeutic exercise bicycle with measuring instrumentation, a manually propelled treadmill with